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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,154	06/22/2001	Ramesh Warier	112713-131	8167

29200 7590 10/04/2004

BAXTER HEALTHCARE CORPORATION
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DEERFIELD, IL 60015

EXAMINER

MACHUGA, JOSEPH S

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,154

Applicant(s)

WARIAR ET AL.

Examiner

Joseph S. Machuga

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-14,17-21,23-27,29,30 and 32-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 5-14, 17-21, 23-27, 29, 30, 32-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Response to Amendment

Applicant's arguments have been given careful consideration but are not deemed persuasive. The Johnson reference clearly teaches the use of a capacitive type sensor to detect the presents of fluid. The motivation to use that type of sensor in the WO99/24145 device is provided for by Johnson, namely to provide a sensor that is cheap and reusable. The two systems are considered analogous since they are both moisture detectors. Accordingly the rejection is considered proper.

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 5-14, 17-21, 23-27, 29, 30, 32-34, 36 and 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/24145 in view of Johnson #5469145.
3. WO 99/24145 discloses a blood line separation warning device. As illustrated in Figures 2 and 3 the device includes a sensor and sensor holder. The reference notes on page 8 lines 16-21 that the presents of blood within the patch creates a conductive path between the electrodes to close the circuit and send a signal indicating that needle dislodgement has occurred.

4. Johnson discloses a fluid detector. As illustrated in Figures 10-13 the device included a holder (122) and a circular shaped capacitive sensor. The sensor assembly is releasably attached to the outer layer of material and is located within a cavity (note fig 10.) The device measures the change in capacitance of this cloth layer to record changes in moisture. The design as noted in column 4, lines 1-37 is highly efficient relative to the prior art. The reference also notes that no component extends into the garment.

5. Given the teaching of Johnson it would have been obvious to one of ordinary skill in the art to use a capacitance type sensor in place of the electrodes in WO 99/24145 to produce a design that is inexpensive and highly efficient. Regarding claim 11: To locate the sensor within a cavity would have been obvious to one of ordinary skill in the art given Johnson's teaching of this to make the sensor reusable.

Regarding claim 9 and 25 the control device is attached to the patient through lines 13, 17, 42A and 42B as clearly illustrated in Figure 1. Regarding method claims 27, 29, 30, 32-34, 36 and 37, as illustrated in Figures 2 and 3 of WO 99/24145 the device includes a cutout portion enabling the sensor to be added *after* the needle has been inserted. Given this, it would have been obvious to one of ordinary skill in the art to position the sensor on the patient *after* the needle is in place since it is one of two obvious and readily apparent possibilities and since this arrangement would allow for a clear

unobstructed view of the vein which would not be the case if the sensor was already in place on the patient.

6. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/24145 in view of Johnson #5469145 as applied to claim 33 above, and further in view of either WO 97/10013, Shintani et al #4181610 or JP 104233.

7. WO 97/10013, Shintani et al and JP 104233 all teach closing a control a valve in response to blood leakage. WO 99/24145 teaching that if leakage is detected corrected action to minimize blood lose should be taken (column 7, lines 15-18.)

8. It would have been obvious to one of ordinary skill in the art to shut off a clamp/valve in the fluid line of the WO 99/24145 device when a leak is detected given that WO 99/24145 suggests that corrective actions should take place in response to blood loss and given that it is old and well known to close a clamp/valve given the teachings of either WO 97/10013, JP104233 or Shintani et al.

9. Claims 1, 5-7 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al (5579765) in view of Johnson #5469145.

10. Cox et al discloses a blood leakage sensor. As illustrated in Figure 3 the device includes sensor elements 36-38 that are mounted within a pocket formed between gauze layers 32 and top surface 48. The device also includes a control device mounted

on the patient. The device is used to detect external bleeding when the gauze layer becomes wet with either sweat or blood. Not disclosed by this reference is the use of a capacitance type sensor.

11. Johnson discloses a fluid detector. As illustrated in Figures 10-13 the device included a holder (122) and a capacitive sensor. The sensor assembly is releasably attached to the outer layer of a garment. The device measures the change in capacitance of the cloth layer to record changes in moisture. This feature makes the sensor reusable since it never comes in contact with the fluid.

12. Given Johnson's disclosure it would have been obvious to one of ordinary skill in the art to use a capacitive type sensor in Cox et al's device mounted on gauze or similar material to measure the presents of blood without direct contact so as to make the sensor reusable.

13. Claims 8, 9, 11-14, 17-21 and 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cox et al (5579765) in view of Johnson #5469145 as applied to claims 1, 5-7 and 10 above and further in view of WO 99/24145.

WO 99/24145 teaches that it is old and well known to use a blood leakage detector in a hemodialysis machine. The reference also teaches taking the signal from the sensor and feeding it to the machine. Given this teaching it would have been obvious to one of

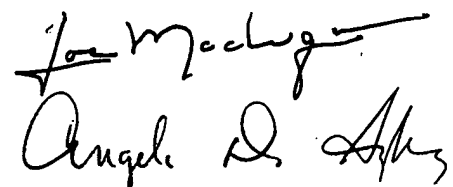
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ordinary skill in the art to use the device of the proposed combination in a hemodialysis machine. To take the ~~out~~^{output} of the sensor and feed it into the machine to control it would have been obvious to one of ordinary skill in the art given WO 99/24145's teaching that this is old and well known.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph S. Machuga whose telephone number is 703-305-6184. The examiner can normally be reached on M-F 6:30-3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela D Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Handwritten signature of Angela D. Sykes in black ink.

ANGELA D. SYKES
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700